

To: CN=Katherine Baylor/OU=R9/O=USEPA/C=US@EPA;CN=John Moody/OU=R9/O=USEPA/C=US@EPA[]; N=John Moody/OU=R9/O=USEPA/C=US@EPA[]
Cc: CN=Steve Armann/OU=R9/O=USEPA/C=US@EPA;CN=Caleb Shaffer/OU=R9/O=USEPA/C=US@EPA[]; N=Caleb Shaffer/OU=R9/O=USEPA/C=US@EPA[]
Bcc: []
From: CN=Patrick Wilson/OU=R9/O=USEPA/C=US
Sent: Thur 10/18/2012 4:47:06 PM
Subject: GTE/Mtn View Site TCE Contamination: Inside EPA Article on "Intermediate" Exposures to TCE, FYI
[convening a panel Health Consultation have said](#)

Additional context for TCE exposure & its relationship to cardiac malformations during gestation:

----- Forwarded by Patrick Wilson/R9/USEPA/US on 10/18/2012 09:44 AM -----

From: Rich Kapuscinski/DC/USEPA/US
To: OSWER OSRTI Human Health Risk Assessors,
Date: 10/18/2012 07:00 AM
Subject: Inside EPA Article on "Intermediate" Exposures to TCE, FYI

ATSDR Finds Increased Health Risks From Intermediate TCE Exposure

Posted: September 5, 2012

The Agency for Toxic Substances & Disease Registry (ATSDR) is warning that residents in a Delaware town may have suffered an increased chance of health risks, including cardiac birth defects and kidney effects, from a roughly one-year exposure to trichloroethylene (TCE) that contaminated municipal drinking water, adding to an ongoing debate about the risks from short-term and intermediate exposures to the solvent. The reevaluation of the town's health risks is a result of EPA's 2011 Integrated Risk Information System (IRIS) assessment for TCE, which increased the solvent's toxicity and added cardiac birth defects as a possible effect of short-term exposure.

The findings of increased risk come as EPA and industry are debating how best to assess the risk of non-cancer effects from short-term or intermediate exposures to TCE since the IRIS assessment focused on chronic, or long-term exposure.

EPA headquarters is currently considering the question as part of a weight-of-evidence assessment requested by EPA's Region IX and industry officials who oppose Region IX's proposed interim Removal Action Level (RAL) of 15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) in indoor air, which is aimed at protecting workers near the Middlefield-Ellis-Whisman Superfund site in Mountain View, CA, from cardiac birth defects. Additionally, the nonprofit Alliance for Risk Assessment, a group of environmental consultants and other risk experts, is convening a panel to consider the exposure duration issue and other concerns surrounding EPA's recent TCE policy.

ATSDR's Aug. 17 Health Consultation for Millsboro, DE, finds that past exposure to TCE in Millsboro's once-contaminated water supply may have increased residents' risk of non-cancer health hazards, including cardiac birth defects as well as immunological and kidney effects. The study also found increased risk of cancer but ATSDR says the risk is low. ATSDR is taking public comment on the document until Sept. 17. "The reevaluation suggests a wider range of potential health effects from past TCE exposures" than were considered in the prior draft released for public comment in 2011, before EPA finalized its TCE IRIS assessment, according to the ATSDR report. In the fall of 2011, no one from the public submitted comments.

Additionally, ATSDR says Millsboro's water poses no health risks now or in the future because filtration systems ensure TCE levels remain below EPA's maximum contaminant level (MCL) of 5 parts per billion (ppb). In addition, the Millsboro Water Treatment Facility does weekly sampling and reports any samples

above 0.5 ppb, which is below ATSDR's most protective guidelines.

The new Health Consultation considers possible exposure to TCE through vapor intrusion and drinking water, as well as through inhalation and skin contact while showering and washing dishes or doing laundry with contaminated water.

Discovery Of Contamination

Although the exact date when Millsboro's water became contaminated is unknown, ATSDR says TCE from a poultry vaccine manufacturing plant leaked into soil, then groundwater, and then contaminated the town's municipal water supply sometime between water tests in October 2004 and the contamination's discovery in October 2005. After TCE was found in two of Millsboro's three water supply wells, residents were warned against drinking town water, and by December of 2005, a granulated activity carbon filtration system had mitigated the problem, according to ATSDR's health assessment.

Given those circumstances, ATSDR's analysis estimates a maximum exposure duration of one year, one of several conservative or "health protective" estimates ATSDR says it included in its risk calculations, a process that involved wrestling with several unknown factors.

With only one sample of 80 ppb from a point where someone would have been exposed, ATSDR says scientists calculated dose estimates from supply well samples taken at the water treatment plant even though actual exposure doses might have been less, either because TCE evaporated before reaching residents' taps, or because people may have lowered their exposure by using a carbon filter available on the market, provided they followed manufacturers' instructions on filter use and replacement.

With estimated exposure doses exceeding the reference values included in EPA's IRIS assessment, and without suitable comparison values for intermediate exposure durations such as the estimated one-year exposure, ATSDR compared its estimated exposure doses to human equivalent doses, which EPA derived from animal studies and included in the IRIS assessment. The human equivalent doses and concentrations ATSDR used for ingestion and inhalation were derived from animal studies by taking into account physiologic and pharmacokinetic differences in animal models and humans, ATSDR's health consultation says.

While evaluating exposure from drinking water, ATSDR compared its estimated exposure doses to the human equivalent doses from the three principal and two supporting studies that EPA used to set its reference dose, or estimated safe level of exposure for a lifetime of ingestion of TCE.

The animal studies include a 2003 study by Paula D. Johnson, which found a risk of cardiac birth defects in rats, as well as several other studies that found immunological effects in mice or kidney effects in rats.

After comparing its estimated exposures to EPA's human equivalent doses, ATSDR concluded that pregnant women who drank unfiltered water may have had an increased likelihood of adverse fetal cardiac effects. And while none of the exposure from drinking contaminated water should have affected immune systems, ATSDR found that "children and adults, who drank unfiltered TCE-contaminated water may have had an increased likelihood of adverse effects to their kidneys."

ATSDR conducted a similar analysis for inhalation exposure from showering, and compared its estimated exposure concentration to the two underlying studies on which EPA based its reference concentration for lifetime inhalation exposure. Those studies were the Johnson study and a 2009 study which found decreased thymus weight in mice, and from which EPA derived developmental, immunologic and kidney effects in humans.

By comparing estimated exposure concentrations to health effects from those studies, ATSDR found a possibility of "an increased likelihood of adverse" immunological effects and cardiac birth defects as a result of inhaling TCE from water while showering.

Vapor Intrusion Study

The study found no confirmation of vapor intrusion, but the report says the indoor air samples collected were not directly above the contamination, and so additional testing for vapor intrusion will be done in the future.

The discovery of increased health risks in Millsboro is one of a series of steps government agencies have taken to inform or protect the public since the September 2011 IRIS assessment for TCE increased the toxicity of the ubiquitous solvent, and added health risks that raised concerns about how to regulate short-term and intermediate exposures.

In addition to Region IX's proposed RAL, EPA's Region III has announced a plan to offer mitigation systems to more residents to prevent vapor intrusion from causing dangerous levels of TCE in indoor air in homes near the Crossley Farm Superfund site in Berks County, PA. Region III already offered mitigation in some homes, and officials have said they plan to offer government-funded mitigation to more homeowners who live near the site's highly

contaminated groundwater, in part because of the IRIS assessment. Some of the homes would have received the mitigation anyway, Region III officials have said.

Meanwhile, concerns about short-term exposures to TCE, a new risk stemming from the inclusion of cardiac birth defects as a health risk in the TCE IRIS assessment, has led environmentalists to ask EPA to include strict new monitoring requirements in its upcoming vapor intrusion guidance. Vapor intrusion occurs when toxic vapors rise into indoor air from below ground contamination through dirt floors, cracks in foundations or other pathways.